

REMARKS

By this Amendment, claims 97-100 are newly added. Consequently, claims 1-8, 10-21, 23-54, and 56-100 are pending in this application, with claims 1, 19, 34, 47, 59, 69, 83, and 87 being independent.

As an initial matter, Applicant wishes to express sincere appreciation to the Examiner and his supervisor (Ms. Linda Dvorak) for the courtesy extended to Applicant's representative during the personal interview held on August 31, 2006. At the interview, various rejections outstanding in the final Office Action were discussed. The following remarks reflect the subject matter discussed during the interview.

Finality of June 6, 2006 Office Action

As discussed during the interview, the finality of the June 6, 2006 Office Action is premature and should be withdrawn. In that Office Action, certain claims are rejected under 35 U.S.C. § 112, second paragraph, and claim 93 is rejected under 35 U.S.C. § 103(a). These rejections, raised for the first time in that Office Action, however, are not necessitated by Applicant's amendment because Applicant's last response filed May 3, 2006 did not amend any claims. Therefore, the finality of the June 6, 2006 Office Action improperly precludes Applicant's full and fair opportunity to respond to that Office Action and, therefore, should be withdrawn, as agreed upon during the August 31, 2006 interview.

35 U.S.C. § 112, Second Paragraph, Rejection

Claims 1, 11-13, 18-20, 25, 26, 34, 42, 59, 69, 72, 73, 75, 77, 79, 80, 83, 85-87, 92, and 96 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. As an outcome of the interview, the Examiner agreed to withdraw this rejection.

35 U.S.C. § 103(a) Rejection Based on Konomura and Levinson

Claims 1-4, 8, 10-18, 23-30, 33-40, 42-44, 46, 47-52, 54, 56, 58-63, and 65-68 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura ("Konomura") in view of U.S. Patent No. 6,660,011 to Levinson ("Levinson"). See pages 3-6 of final Office Action. For the following reasons, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Each of independent claims 1 and 34 is directed to a medical device including "an elongated member" and "a tissue cutting end effector proximate the distal end of the elongated member." Claim 1 further recites, among other things, "a distal member," whereas claim 34 recites, among other things, "a nozzle member."

Each of independent claims 47 and 59 is directed to a method of performing a medical procedure. Claim 47 recites "inserting a medical device into a tissue tract of a patient," the medical device including a nozzle member and a tissue cutting end effector. The method further includes "actuating the tissue cutting end effector of the medical device to sever the tissue of the tissue tract." Claim 59 recites "inserting a medical device into a patient," the medical device including an elongated member, a tissue cutting end effector, and a distal member. The method further includes "actuating the tissue cutting end effector to sever tissue of a tissue tract."

In the rejection, the final Office Action admits that Konomura does not disclose "a tissue cutting end effector wherein actuation of the proximal handle causes the end effector to sever tissue." (See page 3.) Nonetheless, the final Office Action asserts that "Levinson teaches of an analogous medical device used for tissue cutting and retrieval" and that "[i]t would have been obvious ... to have a tissue cutting end effector in the apparatus of Konomura to selectively capture, cut and/or retrieve polyps and other

aggregates of organic tissue' from a patient's internal organs as taught by Levinson.”

Applicant respectfully submits that the final Office Action's asserted combination of Konomura and Levinson fails to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a).

The Examiner has the initial burden of presenting a *prima facie* case of unpatentability. To establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a), three basic criteria must be met. First, the prior art references when combined must teach or suggest all the claim elements. Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Finally, there must be a reasonable expectation of success. See M.P.E.P. § 2143. Furthermore, case law in this context indicates that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and that the evidence of a teaching, suggestion, or motivation to combine must be “clear and particular.”

Konomura discloses a basket forceps assembly 1 comprising a hollow sheath 2 and a basket 3 that moves out of and into the front end of the sheath 2 for holding or fracturing a foreign matter. The basket 3 comprises a plurality of resilient wires 6 and a front end tip 7 to which the front ends of the wires 6 are secured. The Konomura basket is for holding or fracturing calculi, stones, and the like found within the urologic tract, such as the bile duct or ureter. The basket is not for severing tissue from a tissue tract.

Different from the basket forceps assembly 1 of Konomura, Levinson discloses a device 10 for cutting and retrieving tissue. The device includes a handle 12, an

elongated tube 14 extending from the handle 12, and first and second sets of wires 20, 28 slidable relative to the tube 14. A control tip 24 is secured to the distal ends 22 of the first set of wires 20. See, e.g., Figs. 2 and 3. To cut and retrieve tissue in a body cavity, as shown in Fig. 9, after the distal end of the tube 14 is inserted into the body cavity, the second set of wires 28 is first extended from the distal end of the tube 14 to capture and cut tissue. The first set of wires 20 and the control tip 24 of the first wires are then extended from the distal end of the tube to capture the cut tissue between the first and second sets of wires 20, 28. Thereafter, the distal end of the tube 14, together with the first and second sets of wires, is withdrawn from the body cavity. See also col. 5, lines 39-57.

As detailed below, the asserted combination of Konomura and Levinson fails to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a). In particular, as to the second criterion for establishing a *prima facie* case of obviousness, there is no suggestion or motivation in either Konomura or Levinson to combine or modify the asserted teachings of the references in the manner proposed by the final Office Action. The final Office Action asserts that, since Levinson discloses an end effector that cuts and retrieves tissue, it would have been obvious to have Levinson's end effector in the device of Konomura "to selectively capture, cut and/or retrieve polyps and other aggregates of organic tissue from a patient's internal organs as taught by Levinson." However, this asserted motivation is merely a conclusory statement and does not provide any sufficient, factual reasoning as to why selectively capturing, cutting, and/or retrieving polyps and other aggregates of organic tissue would have been desired by one of ordinary skill in the art considering Konomura's device. For example, there is no

teaching or suggestion in Konomura that its basket forceps assembly needs or desires a tissue cutting capability. Nor does Levinson teach or suggest that it does. Although Levinson teaches combining a tissue cutting snare and a basket retriever in one device to cut and retrieve tissue, it does not teach that such a tissue cutting capability is desirable in the device of Konomura, which is typically used in urology applications to hold or fracture a gallstone or ureteral calculus. Thus, there is no clear and particular reason supplied by either Konomura or Levinson that would have motivated one skilled in the art to modify the basket forceps assembly of Konomura in the manner proposed by the final Office Action.

The final Office Action's asserted motivation is a result of impermissible hindsight gleaned from the present application, which discloses novel and non-obvious subject matter of, for example, a tissue cutting end effector having a spray mechanism. When the references are viewed without such hindsight, one of ordinary skill in the art considering Konomura's device would not have been motivated to modify the device in the manner proposed by the final Office Action since there is no "clear and particular" reason to do so. For at least these reasons, a *prima facie* case of obviousness under 35 U.S.C. § 103(a) has not been properly established.

Moreover, with respect to method claims 47-54, 56-68, and 89-96, the final Office Action asserts that "[t]he apparatus of Konomura and Levinson is inherently capable of performing the recited method steps." Applicant respectfully disagrees with this assertion because the final Office Action has improperly relied on an inherency principle.

For a proper inherency-based rejection, the Office must provide a factual basis and/or technical reasoning to reasonably support its determination that the missing feature is necessarily present in the subject matter described in the reference. In general, mere probabilities or possibilities that certain subject matter may result from a given set of circumstances is not sufficient to establish inherency. See generally M.P.E.P. § 2112. Thus, whether a device in a prior art reference is inherently capable of performing recited method in a claim is completely irrelevant in determining whether that reference discloses the method. Instead, to properly rely on the inherency principle, the Office must show that the normal and usual operation of the device in the prior art reference must necessarily perform the recited method. See, e.g., M.P.E.P. 2112.02.

Therefore, the rejection of claims 47-54, 56-68, and 89-96 based on the assertion that “[t]he apparatus of Konomura and Levinson is inherently capable of performing the recited method steps” is erroneous.

Furthermore, it is not even clear what the so-called “apparatus of Konomura and Levinson” would be and what applications it would have. Consequently, it is unclear what “the normal and usual operation” of that apparatus would be. Since the “the normal and usual operation” of that apparatus is unclear, relying on the inherency principle and asserting that the apparatus inherently teaches all of the recited methods is baseless.

For at least the reasons set forth above, reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a) is respectfully requested.

35 U.S.C. § 103(a) Rejection Based on Konomura, Levinson, and McAlister

Claims 5-7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Konomura in view of Levinson and further in view of U.S. Patent No. 5,599,324 to McAlister et al. ("McAlister"). See page 6 of final Office Action. Applicant respectfully requests reconsideration and withdrawal of this rejection since claims 5-7 depend directly or indirectly from independent claim 1. As discussed above, independent claim 1 patentably distinguishes from the asserted combination of Konomura and Levinson, and McAlister does not supply the deficiency of Konomura and Levinson.

35 U.S.C. § 103(a) Rejection Based on Konomura, Levinson, and Smith

Claims 19-21, 41, 57, 83-86, 90-92, and 94-96 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Konomura in view of Levinson and further in view of U.S. Patent No. 6,517,539 to Smith et al. ("Smith"). See pages 6 and 7 of final Office Action. As an outcome of the interview, the Examiner agreed to withdraw this rejection.

35 U.S.C. § 103(a) Rejection Based on Konomura, Levinson, and Hawkins

Claims 31, 32, 45, 53, and 64 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Konomura in view of Levinson and further in view of U.S. Patent No. 5,575,694 to Hawkins et al. ("Hawkins"). See page 7 of final Office Action. Applicant respectfully requests reconsideration and withdrawal of this rejection, since each of these claims depends directly or indirectly from independent claim 1, 34, 47, or 59. As discussed above, independent claims 1, 34, 47, and 59 patentably distinguish from the asserted combination of Konomura and Levinson, and Hawkins does not supply the deficiency of Konomura and Levinson.

35 U.S.C. § 103(a) Rejection Based on Konomura, Levinson, and Moutafis

Claims 47, 59¹, 69-82, 87-89, and 93 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Konomura in view of Levinson and further in view of U.S. Patent No. 6,960,182 to Moutafis et al. ("Moutafis"). See page 8 and 9 of final Office Action. As an outcome of the interview, the Examiner agreed to withdraw this rejection.

New Dependent Claims 97-100

Applicant adds dependent claims 97-100, which depend from independent claims 1, 34, 47, and 59, respectively. As agreed upon during the interview, the subject matter of these claims (i.e., reciting that the tissue cutting end effector consists essentially of a snare loop) clearly further distinguishes from the alleged combination of Konomura and Levinson.

Conclusion

Applicant respectfully requests reconsideration of this application, withdrawal of all of the outstanding rejections, and allowance of all pending claims.

The final Office Action contains a number of statements and characterizations regarding the claims and the related art. Applicant declines to necessarily subscribe to any statement or characterization in the final Office Action, regardless of whether it is addressed above.

Should the Examiner wish to discuss this case, he is invited to call the undersigned at 202-408-4140.

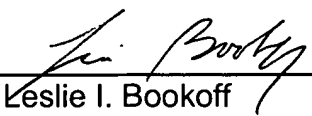
¹ Applicant notes that claim 59 is also rejected earlier under 35 U.S.C. § 103(a) based on Konomura in view of Levinson. See page 3 of final Office Action. During the interview, the Examiner clarified that claim 59 was mistakenly included in this rejection.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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